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| EXAMINER | |
|---|---|
| DOWELL, PAUL THOMAS | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,154 | MORISHITA ET AL. | |
| | Examiner | Art Unit | |
| | Paul Dowell | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,6 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/05,3/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

Applicant's have canceled claims 2, 4-5, 7-8, amended claims 1 and 6 and newly added claims 12-15 in the response of 3/3/2006. Claims 1, 3, 6 and 12-15 are currently pending.

***Information Disclosure Statement***

Response to Arguments

Applicant's arguments, see page 6, filed 3/3/2006, with respect to the information disclosure statement filed 3/7/2005 have been fully considered and are persuasive. Applicants have provided an English translation of the parts of Ishida et al that are relevant to the instant application. Examiner has considered only those parts of Ishida that are in English.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response to Arguments

Applicant's arguments, see page 6, filed 3/3/2006, with respect to the rejection(s) of claim(s) 1-4, 6, 7 and 11 under the judicially created obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent 6,936,594 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

New Double Patenting Rejection

Claims 1, 3, 6, 12-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5 of U.S. Patent No. 6,936,594 (hereafter referred to as '594) in view of Hayashi et al **(Gene Therapy, 8:1167-1173, 2001, IDS)** and Barnes et al **(Journal of Lipid Research, 28:130-137, 1987)**.

Claims 1, 3, 6, 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 5 of **U.S. Patent No. 6,936,594 (cited on PTO-892 of 11/3/2005)** (hereafter referred to as '594). Although the conflicting claims are not identical, they are not patentably distinct from each other because said claims of the instant application and claims 1, 2, 4 and 5 of the cited patent are both drawn to a method of treating co-extensive cerebrovascular

disorders (i.e. cerebral infarction which is a cerebral vascular disorder encompassing reduced blood flow to the brain and neuronal death) comprising administration of a nucleic acid encoding hepatocyte growth factor wherein said nucleic acid is in the form of HVJ-envelope.

The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from "HVJ-liposome", as recited in the claims of the cited patent. Specifically, '594 discloses that the production of HVJ-liposome comprises the steps of UV inactivating HVJ followed by mixing DNA containing liposomes with the inactivated HVJ (col. 11, lines 6-21). The specification of the instant application discloses that the production of HVJ envelope comprises the steps of UV inactivating HVJ, mixing DNA and detergent with the inactivated HVJ and removing the detergent (page 18, lines 10-23). It was well known in the art of record at the time of the invention that typical liposome preparations consisted of phosphatidylserine, phosphatidylcholine and cholesterol. For example, Hayashi teaches production of HVJ-liposome as described above using a liposomal mixture containing phosphatidylserine, phosphatidylcholine and cholesterol (page 1171, col. 2, paragr. 1). Further, Barnes teaches that Sendai viral envelopes are composed of phosphatidylserine, phosphatidylcholine and cholesterol (see Abstract and page 132, col. 1, paragr. 1). As such, the HVJ-liposome of the cited patent and the HVJ-envelope of the instant application cannot be structurally distinguished (i.e. both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine and cholesterol) based upon the disclosures of either the cited patent or the instant application.

The claims of the present application and the cited patent differ one from the other in that the instant claims may comprise a nucleic acid encoding a protein effective as a hepatocyte growth factor while the claims of the cited patent may further comprise a nucleic acid encoding vascular endothelial growth factor, however, both the claims of the instant application and the claims of the cited patent encompass a hepatocyte growth factor gene alone in the form of HVJ-liposome/HVJ-envelope. It is noted that the product claims of the instant application (claims 1, 3 and 13) are required for the method claimed in the cited patent. Accordingly, the inventions as claimed are co-extensive.

***Claim Objections***

Response to Arguments

Applicant's arguments, see page 6, filed 3/3/2006, with respect to the objection to claims 4, 5, 8 and 11 have been fully considered and are persuasive. The instant objection to claims 4, 5, 8 and 11 has been withdrawn.

***Specification***

Response to Arguments

Applicant's arguments, see page 5, filed 3/3/2006, with respect to the objection to the abstract and to the specification has been fully considered and are persuasive. The objection to the abstract and the objection to the specification have been withdrawn.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Response to Arguments

Applicant's arguments, see page 7, filed 3/3/2006, with respect to the rejection of claims 1-8 and 11 under 35 U.S.C. § 101 have been fully considered and are persuasive. The instant rejection of claims 1-8 and 11 has been withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Response to Arguments

Applicant's arguments, see page 7, filed 3/3/2006, with respect to the rejection of claims 1-8 and 11 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement have been fully considered and are persuasive. The instant rejection of claims 1-8 and 11 has been withdrawn.

Enablement

Response to Arguments

Applicant's arguments, see pages 7 and 8, filed 3/3/2006, with respect to the rejection of claims 1-8 and 11 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement have been fully considered and are persuasive. The instant rejection of claims 1-8 and 11 has been withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Response to Arguments

Applicant's arguments, see page 8, filed 3/3/2006, with respect to the rejection of claim 1 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention have been fully considered and are persuasive. The instant rejection of claim 1 has been withdrawn.

New Rejection Under 35 U.S.C. § 112, second paragraph

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the method of claim 1"; however, claim 1 is drawn to an agent. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Response to Arguments

Applicant's arguments, see pages 8-9, filed 3/3/2006, with respect to the rejection of claims 1-4, 6, 7 and 11 under 35 U.S.C. § 102(b) and under 35 U.S.C. § 102(e) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made.

New Rejections Under 35 USC § 102(b)

Claims 1, 3, 6, 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Morishita et al **(Australian Patent Application No. 200073148, published 4/24/2001, now Patent No. 774990, cited on PTO-892 of 11/3/2005)** as evidenced by Hayashi et al **(Gene Therapy, 8:1167-1173, 2001, IDS)** and Barnes et al **(Journal of Lipid Research, 28:130-137, 1987)**.

Morishita et al teaches an agent for cerebrovascular disorders comprising a hepatoctye growth factor gene as an active ingredient wherein said cerebrovascular disorders comprise a cerebral infarction (Claims 1 and 2). Morishita et al teaches said agent further comprising an HVJ-liposome (page 22, lines 6-18). Morishita et al also teaches a therapeutic or preventive method for cerebrovascular disorders comprising introducing into a human subject a nucleic acid encoding hepatocyte growth factor (Claim 13). Morishita et al teaches said method to treat cerebral infarctions (page 19, line 8). Further, Morishita et al teaches said method wherein the introduction of the nucleic acid encoding hepatocyte growth factor comprises introducing the nucleic acid by HVJ-liposomes (page 22, lines 6-18).

The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from the "HVJ-liposome" taught by Morishita et al. Specifically, Morishita discloses that the production of HVJ-liposome comprises the steps of UV inactivating HVJ followed by mixing DNA containing liposomes with the inactivated HVJ (page 27, lines 9-24). The specification of the instant application discloses that the production of HVJ envelope comprises the steps of UV inactivating HVJ, mixing DNA and detergent with the inactivated HVJ and removing the detergent (page 18, lines 10-23). It was well known in the art of record at the time of the invention that typical liposome preparations consisted of phosphatidylserine, phosphatidylcholine and cholesterol. For example, Hayashi teaches production of HVJ-liposome as described above using a liposomal mixture containing phosphatidylserine, phosphatidylcholine and cholesterol (page 1171, col. 2, paragr. 1). Further, Morishita

teaches a lipsomal mixture containing phosphatidylserine, phosphatidylcholine and cholesterol (page 26, lines 25). Still further, Barnes teaches that Sendai viral envelopes are composed of phosphatidylserine, phosphatidylcholine and cholesterol (see Abstract and page 132, col. 1, paragr. 1). As such, the HVJ-liposome taught by Morishita and the HVJ-envelope of the instant application cannot be structurally distinguished (i.e. both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine and cholesterol). Thus, Morishita et al anticipates the claimed invention.

It is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP recites (see 2111.02), "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

Claims 1, 3, 6, 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al **(Gene Therapy, 8:1167-1173, 2001, IDS)** as evidenced by Barnes et al **(Journal of Lipid Research, 28:130-137, 1987)**.

Hayashi teaches an agent comprising a nucleic acid encoding human HGF in the form of an HVJ-liposome suspension (page 1171: col. 1, paragr. 2 and col. 2, paragr. 1).

Hayashi teaches a method of injecting said agent into the cisterna magna for infusion into the subarachnoid space of the brain of gerbils (page 1171, col. 2, paragr. 2). Hayashi teaches that administering said agent as such, followed by carotid artery occlusion, prevents ischemic neuronal death (page 1168, col. 1, paragr. 3 to page 1170, col. 1, paragr. 1).

The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from the "HVJ-liposome" taught by Hayashi. Specifically, Hayashi discloses that the production of HVJ-liposome comprises the steps of UV inactivating HVJ followed by mixing DNA containing liposomes with the inactivated HVJ and teaches a liposomal mixture containing phosphatidylserine, phosphatidylcholine and cholesterol (page 1171, col. 2, paragr. 1). The specification of the instant application discloses that the production of HVJ envelope comprises the steps of UV inactivating HVJ, mixing DNA and detergent with the inactivated HVJ and removing the detergent (page 18, lines 10-23). Barnes teaches that Sendai viral envelopes are composed of phosphatidylserine, phosphatidylcholine and cholesterol (see Abstract and page 132, col. 1, paragr. 1). As such, the HVJ-liposome taught by Hayashi and the HVJ-envelope of the instant application cannot be structurally distinguished (i.e. both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine and cholesterol). Thus, Hayashi et al anticipates the claimed invention.

It is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on

the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP recites (see 2111.02), "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

New Rejection Under 35 USC § 102(e)

Claims 1, 3, 6, 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Morishita et al **(U.S. Patent No. 6,936,594, cited on PTO-892 of 11/3/2005)** as evidenced by Hayashi et al **(Gene Therapy, 8:1167-1173, 2001, IDS)** and Barnes et al **(Journal of Lipid Research, 28:130-137, 1987)**.

The applied reference (i.e. Morishita et al) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Morishita teaches a method of treating cerebrovascular disorders (claim 1), treating reduced blood flow (claim 2), promoting cerebral angiogenesis (claim 3), suppressing neuronal death (claim 4) and suppressing apoptosis of nerve cells (claim 5)

comprising administration of a nucleic acid encoding hepatocyte growth factor in the form of HVJ-liposome.

Claims 1-5 of the cited patent and claims 6, 12, 14 and 15 of the instant application are drawn to a method of treating co-extensive cerebrovascular disorders (i.e. cerebral infarction which is a cerebral vascular disorder encompassing reduced blood flow to the brain and neuronal death) comprising administration of a nucleic acid encoding hepatocyte growth factor wherein said nucleic acid is in the form of HVJ-envelope.

The basis of the instant rejection is that "HVJ-envelope", as recited in the claims of the instant application, is not distinct from "HVJ-liposome", as recited in the claims of the cited patent. Specifically, '594 discloses that the production of HVJ-liposome comprises the steps of UV inactivating HVJ followed by mixing DNA containing liposomes with the inactivated HVJ (col. 11, lines 6-21). The specification of the instant application discloses that the production of HVJ envelope comprises the steps of UV inactivating HVJ, mixing DNA and detergent with the inactivated HVJ and removing the detergent (page 18, lines 10-23). It was well known in the art of record at the time of the invention that typical liposome preparations consisted of phosphatidylserine, phosphatidylcholine and cholesterol. For example, Hayashi teaches production of HVJ-liposome as described above using a liposomal mixture containing phosphatidylserine, phosphatidylcholine and cholesterol (page 1171, col. 2, paragr. 1). Further, Barnes teaches that Sendai viral envelopes are composed of phosphatidylserine, phosphatidylcholine and cholesterol (see Abstract and page 132, col. 1, paragr. 1). As

such, the HVJ-liposome of the cited patent and the HVJ-envelope of the instant application cannot be structurally distinguished (i.e. both comprise DNA encoding HGF, phosphatidylserine, phosphatidylcholine and cholesterol) based upon the disclosures of either the cited patent or the instant application. Thus, Morishita anticipates the claimed invention of the instant application.

It is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP recites (see 2111.02), "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicant's arguments, see page 9-10, filed 3/3/2006, with respect to the rejection of claims 5 and 8 under 35 U.S.C. § 103(a), have been fully considered and are persuasive. The instant rejection of claims 5 and 8 has been withdrawn.

***Conclusions***

No claims are allowed.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment and provide any statements that might help to identify support for the claimed invention (e.g. if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is 571-272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Dowell
Art Unit 1632

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER